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WHAT IS CLAIMED IS:

1   1.   A monoclonal antibody or an antigen-binding fragment thereof reactive
2   with *in vivo* produced advanced glycosylation endproducts (AGEs), which
3   monoclonal antibody or antigen binding fragment thereof demonstrates an
4   immunological binding characteristic of monoclonal antibody 4G9 as produced by
5   hybridoma 4G9, deposited with the American Type Culture Collection (ATCC)
6   and assigned Accession Number CRL 11626.

1   2.   The monoclonal antibody or antigen-binding fragment thereof of Claim 1,
2   wherein the immunological binding characteristic is selected from the group
3   consisting of reactivity with serum-AGE proteins, serum-AGE lipids, serum-AGE
4   peptides, LDL-AGE, Hb-AGE, and collagen-AGE.

1   3.   The monoclonal antibody of Claim 1 which is humanized or a chimeric
2   human-murine antibody.

1   4.   The antigen-binding fragment of the monoclonal antibody of Claim 1,
2   selected from the group consisting of a single chain Fv fragment, an F(ab')
3   fragment, an F(ab) fragment, and an F(ab')$_2$ fragment.

1   5.   The monoclonal antibody or fragment thereof of Claim 1 which is a murine
2   IgG isotype antibody.

1   6.   The monoclonal antibody or fragment thereof of Claim 4 which is
2   monoclonal antibody 4G9 as produced by hybridoma 4G9, deposited with the
3   American Type Culture Collection (ATCC) and assigned Accession Number CRL
4   11626.

1   7.   The monoclonal antibody of Claim 1 which is labeled.

1   8.   A hybridoma that produces the monoclonal antibody of Claim 1.

1   9.   A hybridoma that produces is monoclonal antibody 4G9 as produced by

2   hybridoma 4G9, deposited with the American Type Culture Collection (ATCC)

3   and assigned Accession Number CRL 11626.

1   10.   A method for detecting the presence of advanced glycosylation endproducts

2   (AGEs) in a biological sample comprising the steps of:

3   a)   contacting a sample suspected of containing AGEs with the

4   monoclonal antibody or antigen binding fragment thereof of Claim 1 under

5   conditions which allow for the formation of reaction complexes comprising

6   the monoclonal antibody or antigen binding fragment thereof and the

7   AGEs; and

8   b)   detecting the formation of reaction complexes comprising the

9   monoclonal antibody or antigen binding fragment thereof and AGEs in the

10   sample;

11 wherein detection of the formation of reaction complexes indicates the presence of

12 AGEs in the sample.

1   11.   The method of Claim 10 wherein the monoclonal antibody or antigen

2   binding fragment thereof is bound to a solid phase support.

1   12.   The method of Claim 11 which further comprises contacting the sample

2   with a labelled advanced glycosylation endproduct (AGE) in step (a), and

3   removing unbound substances prior to step (b), and wherein the formation of

4   reaction complexes in the sample is detected by observing a decrease in the

5   amount of labelled AGE in the sample.

1   13.   The method of Claim 11, wherein the formation of reaction complexes is

2   observed by detecting the binding of a labelled anti-AGE antibody to the complex

3   of the monoclonal antibody or antigen binding fragment thereof and the AGE.

1   14.   The method of Claim 13, wherein the labelled antibody demonstrates an

2   immunological characteristic selected from the group consisting of reactivity with

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3   serum-AGE proteins, serum-AGE lipids, serum-AGE peptides, LDL-AGE, Hb-

4   AGE, and collagen-AGE.

1   15.   The method of Claim 10 wherein the monoclonal antibody or antigen

2   binding fragment thereof is labelled.

1   16.   The method of Claim 10 wherein an AGE is bound to a solid phase

2   support.

1   17.   The method of Claim 16, which further comprises contacting the sample

2   with an AGE in step (a), and removing unbound substances prior to step (b), and

3   wherein the monoclonal antibody or antigen binding fragment thereof is labelled

4   and the formation of reaction complexes in the sample is detected by observing a

5   decrease in the amount of label.

1   18.   The method according to Claim 10, wherein the AGE is a low density

2   lipoprotein (LDL)-AGE.

1   19.   The method according to Claim 10, wherein the AGE is hemoglobin.

1   20.   A method of detecting the level of advanced glycosylation endproducts

2   (AGEs) in a biological sample comprising the steps of:

3   a)   preparing a series of dilutions of a sample suspected of containing

4   AGEs using known amounts of a dilution buffer;

5   b)   contacting the diluted samples suspected of containing AGEs with

6   the   monoclonal antibody or antigen binding fragment thereof of Claim 1 under

7   conditions which allow for the formation of reaction complexes comprising

8   the monoclonal antibody or antigen binding fragment thereof and the

9   AGEs; and;

10   c)   contacting a known amount of a labeled AGE to the monoclonal

11   antibody or antigen binding fragment thereof, which labeled AGE binds to

12   the monoclonal antibody or fragment thereof not bound by the sample,

13   detecting the extent of formation of reaction complexes comprising the

14   monoclonal antibody or antigen vbinding fragment thereof and labeled

15   AGEs in the sample;

16 wherein detection of the extent of formation of labeled-AGE-antibody complexes is

17 inversely proportional to the level of AGEs in the sample.

1   21.   The method according to Claim 20, wherein the AGE is serum-AGE

2   proteins, serum AGE-lipids, serum-AGE peptides, LDL-AGE, hemoglobin-AGE,

3   or collagen-AGE.

1   22.   A method for evaluating the level of AGEs in a biological sample

2   comprising:

3   (a)   detecting the formation of reaction complexes in a biological sample

4   according to the method of Claim 10; and

5   (b)   evaluating the amount of reaction complexes formed, which amount

6   of reaction complexes corresponds to the level of AGEs in the biological

7   sample.

1   23.   A method for detecting or diagnosing the presence of a disease associated

2   with elevated AGE levels in a mammalian subject comprising:

3   (a)   evaluating the level of AGEs in a biological sample from a

4   mammalian subject according to Claim 19; and

5   (b)   comparing the level detected in step (a) to a level of AGEs normally

6   present in the mammalian subject;

7   wherein an increase in the level of AGEs as compared to normal levels indicates a

8   disease associated with elevated levels of AGEs.

1   24.   A method for monitoring the course of a disease associated with elevated

2   AGE levels in a mammalian subject comprising evaluating the level of AGEs in a

3   series of biological samples obtained at different time points from a mammalian

4   subject according to the method of Claim 19, wherein an increase in the level of

5   AGEs over time indicates progression of the disease, and wherein a decrease in

6   the level of AGEs over time indicates regression of the disease.

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1   25.   A method for monitoring a therapeutic treatment of a disease associated

2   with elevated AGE levels in a mammalian subject comprising evaluating the levels

3   of AGEs in a series of biological samples obtained at different time points from a

4   mammalian subject undergoing a therapeutic treatment for a disease associated

5   with elevated AGE levels according to the method of Claim 19, wherein a

6   decrease in the level of AGEs over time indicates an effective therapeutic

7   outcome.

1   26.   A method for detecting the onset and/or monitoring the course of diabetes

2   comprising performing the method of any one of Claims 20 to 22.

1   27.   A method of treating a disease in a patient, one symptom of which is an

2   abnormal level of AGEs, comprising exposing the patient serum to an anti-AGE

3   antibody to form an anti-AGE antibody:AGE complex, and removing the complex

4   from the serum;

5   wherein said anti-AGE antibody comprises a monoclonal antibody of any

6   one of Claims 1-3 or 4.

1   28.   The method of Claim 24 wherein said AGEs are selected from the group

2   consisting of Hb-AGE, LDL-AGE, IgG-AGE, serum-AGE proteins, serum-AGE

3   peptides, and urinary peptide-AGEs.

1   29.   A pharmaceutical composition comprised of a compound which is

2   recognized by and binds to an anti-AGE antibody and inhibits the recognition of

3   AGEs by mammalian AGE receptors, in combination with a pharmaceutically

4   acceptable carrier;

5   wherein said anti-AGE antibody comprises a monoclonal antibody in

6   accordance with any of Claims 1-3 or 4.

1   30.   A pharmaceutical composition containing an anti-AGE antibody in

2   combination with a pharmaceutically acceptable carrier;

3   wherein said anti-AGE antibody comprises a monoclonal antibody in

4   accordance with any of Claims 1-3 or 4.

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1 31.   The pharmaceutical composition of Claim 26 wherein said *in vivo*-produced

2 advanced glycosylation endproducts are selected from the group consisting of Hb-

3 AGE, LDL-AGE, IgG-AGE, serum-AGE proteins, serum-AGE peptides, urinary

4 peptide-AGEs, and combinations thereof.

1 32.   The pharmaceutical composition of Claim 27 wherein said *in vivo*-produced

2 advanced glycosylation endproducts are selected from the group consisting of Hb-

3 AGE, LDL-AGE, IgG-AGE, serum-AGE proteins, serum- AGE peptides, urinary

4 peptide-AGEs, and combinations thereof.

1 33.   A method of treating disease in a mammal, one characteristic of which is

2 an elevated level of AGEs, comprising administering to said mammal an effective

3 amount of the composition of either of Claim 26.

1 34.   A method of treating disease in a mammal, one characteristic of which is

2 an elevated level of AGEs, comprising administering to said mammal an effective

3 amount of the composition of Claim 27.

1 35.   A test kit for measuring the presence or amount of AGEs in an analyte,

2 comprising:

3   a)   a monoclonal antibody or an antigen binding fragment thereof,

4   which monoclonal antibody or antigen binding fragment thereof

5   demonstrates immunological binding characteristics of monoclonal antibody

6   4G9 as produced by hybridoma 4G9, deposited with the American Type

7   Culture Collection (ATCC) and assigned Accession Number CRL 11626;

8   b)   means for detecting the formation of reaction complexes between

9   the monoclonal antibody or antigen binding fragment thereof and AGEs;

10   c)   other reagents; and

11   d)   directions for use of the kit.

1 36.   The test kit of Claim 32, wherein the monoclonal antibody or antigen-

2 binding fragment thereof which is characterized by an activity selected from the

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3   group consisting of reactivity with serum-AGE proteins, serum-AGE lipids,

4   serum-AGE peptides, LDL-AGE, Hb-AGE, and collagen-AGE.

1   37.   The test kit of Claim 32 wherein the anti-AGE antibody is irreversibly

2   associated with a solid phase.

1   38.   The test kit of Claim 32 which further comprises a labelled anti-AGE

2   antibody, which labelled anti-AGE antibody is reactive with *in vivo*-produced

3   AGEs.

1   39.   The test kit of Claim 32 which further comprises a labelled anti-low density

2   lipoprotein antibody.

1   40.   The test kit of Claim 36, wherein the low density lipoprotein is ApoB.

1   41.   The test kit of Claim 32 which further comprises a labelled AGE.

1   42.   The test kit of Claim 32 which further comprises an AGE.

1   43.   The test kit of Claim 39, wherein the AGE is bound to a solid phase and

2   the antibody is labelled.